Certificate

Standard: ISO 13485:2016, JIS Q 13485:2018

Certificate Registr. No.: 81 105 5773

Certificate Holder: Canon Medical Systems Corporation

1385, Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan

including the locations according to annex

Scope: Planning, design, development, manufacturing, installation,

maintenance, distribution, sales and servicing of active medical

devices (diagnostic imaging systems, in vitro clinical test

equipment, picture archiving & communication systems (PACS))

and workstation software

Planning, installation, maintenance, distribution, sales and

servicing of therapeutic equipment

Planning, design, development, manufacturing, distribution and

sales of in vitro diagnostic reagents

Proof has been furnished by means of an audit that the

requirements of ISO 13485:2016, JIS Q 13485:2018 are met.

Validity: The certificate is valid from 2019-10-01 until 2022-09-30.

First certification 2010

2019-09-13

TÜV Rheinland Japan Ltd. 3-19-5 Shin-Yokohama, Kohoku-ku, Yokohama 222-0033, Japan





Annex to certificate

ISO 13485:2016, JIS Q 13485:2018 Standard:

Certificate Registr. No.: 81 105 5773

No.	Location	Scope
/01	Canon Medical Systems Corporation Headquarters 1385 Shimoishigami, Otawara-shi, Tochigi 324-8550, Japan	Planning, design, development, manufacturing, installation, maintenance, distribution, sales and servicing of active medical devices (diagnostic imaging systems, in vitro clinical test equipment, picture archiving & communication systems (PACS)) and workstation software
		Planning, installation, maintenance, sales and servicing of therapeutic equipment
		Planning, design, development, manufacturing, distribution and sales of in vitro diagnostic reagents
/02	Canon Medical Systems Corporation Kawasaki Office 70-1, Yanagi-cho, Saiwai-ku, Kawasaki-Shi, Kanagawa 212-0015, Japan	Sales of active medical devices (diagnostic imaging systems, therapeutic equipment, in vitro clinical test equipment, picture archiving & communication systems (PACS)) and workstation software

Precisely Right.

Annex to certificate

Standard:

ISO 13485:2016, JIS Q 13485:2018

Certificate Registr. No.:

81 105 5773

No.	Location	Scope
/03	Okinawa Canon Medical Systems Co., Ltd. 1-19-9 Nishi, Naha-shi, Okinawa 900-0036, Japan	Installation, maintenance, distribution, sales and servicing of active medical devices (diagnostic imaging systems, therapeutic equipment, in vitro clinical test equipment, picture archiving & communication systems (PACS)) and workstation software

2019-09-13

TÜV Rheinland Japan Ltd. 3-19-5 Shin-Yokohama, Kohoku-ku, Yokohama 222-0033, Japan

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